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Outpatient pharmacy expenditures for the South Texas Veterans Health Care System (STVHCS) have increased at a rate of 1.4% per month; most of this increase can be attributed to an increase in the number of prescriptions being filled. The purpose of this project was to determine if a clinical pharmacy case review program designed to identify prescriptions that should be canceled or changed to cheaper alternatives can avoid sufficient cost to pay for itself.

Two clinical pharmacists reviewed 480 pharmacy profiles and 203 medical records from three random samples. The reviews resulted in the identification of 452 prescription changes. Based on this sample, almost one of every five outpatient prescriptions would be affected if such reviews were instituted system-wide.

Cost-minimization ratios comparing potential cost-avoidance with the cost of labor associated with the review were calculated. These ratios ranged from 2.7 assuming a 45% recommendation implementation rate to 9.5 for a sample of patients with ten or more prescriptions items, assuming a 96% implementation rate. Projecting program savings for the entire STVHCS, at the cost of less than $300,000 for pharmacist labor, a clinical pharmacy case review program could save the system up to $2 million in pharmacy expenditures.

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GRADUATE PROGRAM IN HEALTH CARE ADMINISTRATION

"OUTPATIENT CLINICAL PHARMACY CASE REVIEW WITHIN THE SOUTH TEXAS VETERANS HEALTH CARE SYSTEM"

A GRADUATE MANAGEMENT PROJECT

SUBMITTED TO

THE FACULTY OF BAYLOR UNIVERSITY

IN PARTIAL FULFILLMENT OF THE

DEGREE OF

MASTER OF HEALTH ADMINISTRATION

BY:

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SAN ANTONIO, TEXAS

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ABSTRACT

Outpatient pharmacy expenditures for the South Texas Veterans Health Care System (STVHCS) have increased at an average rate of 1.4% per month over at least the last ten quarters. Most of this increase (greater than 60%) can be attributed to a continuous increase in the number of outpatient prescriptions being filled. The purpose of this project was to determine if a clinical pharmacy case review program designed to identify outpatient prescriptions that should be canceled or changed to cheaper alternatives could avoid sufficient pharmacy cost to pay for itself.

Two clinical pharmacists reviewed 480 pharmacy profiles and 203 medical records from three random samples of STVHCS patients. The reviews resulted in the identification of 452 prescription changes (80% cancellations), each based on one of twelve justifications. Overall, 45% of all pharmacy profiles reviewed had at least one change. Based on this sample, almost one of every five outpatient prescriptions would be affected if such reviews were instituted system-wide.

Cost-minimization ratios comparing potential cost-avoidance with the cost of the labor associated with review were calculated. These ratios ranged from a low of 2.7 ($2.70 saved for every $1 spent on the program) assuming a 45% recommendation implementation rate to a high of 9.5 for a sample of patients with ten or more prescription items, assuming a 96% implementation rate. Potential program savings were projected for the entire STVHCS patient population. At the cost of approximately $290,000 for three, full-time equivalent reviewing pharmacists, a clinical pharmacy case review program could save the STVHCS up to $2 million in outpatient pharmacy expenditures.

Recommendations are made regarding program implementation, outcome measurement, and potential expansion to other federal health care systems.

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CHAPTER 1

INTRODUCTION

General

Expenditures for pharmaceutical supplies for the Audie L. Murphy Memorial Veterans Hospital (ALMMVH) and its satellite clinics have increased steadily over at least the past six fiscal years. Between FY90 and FY94 alone, these expenditures increased by almost 50%. Analysis of pharmacy spending indicates that the cost of in-patient pharmacy remained relatively stable over the past ten quarters and that outpatient cost increases made up most of the total cost increases. Furthermore, both average cost per prescription and outpatient visits per month remained relatively constant over this same time period. Thus, the majority of the increased spending appears to be related to a continuing increase in the number of prescriptions written and filled, relative to the number of outpatient visits.

A great deal of effort could be spent further defining the *why*s and *wherefore*s of pharmacy spending increases. Such efforts might aid in determining if a problem of higher than expected cost increases exists and why the problem(s) is occurring. Alternatively, research time efforts could be spent comparing ALMMVH pharmacy cost with local and national averages. These efforts would allow local managers to compare their track records with those of other health care systems. Such studies would be of

considerable interest from the academic and political perspectives, respectively. However, neither would directly help ALMMVH managers with the problem at hand.

South Texas Veterans Health Care System (STVHCS), the newly organized parent organization for the ALMMVH, managers anticipate that FY96 funding levels for the system will not continue to support increasing pharmacy spending, even if these expenditures remain a fairly constant percentage of the operating budget. Furthermore, Dr. Kenneth W. Kizer, Under Secretary for Health, Department of Veterans Affairs (DVA), recently informed senior medical center managers to expect an actual decrease in funding for FY97. Therefore, it is imperative that ALMMVH managers find more efficient means of operating under an ever-tightening budget as quickly as practicable. This management project supports these efforts to promote efficient spending by determining the extent to which unnecessary outpatient pharmacy expenditures can be reduced through a clinical pharmacy case management program.

ALMMVH Pharmacy Cost Analysis

Prior to attempting to solve a particular problem, one must understand what the problem is. In this case, as originally conceived, the problem to be solved concerned controlling rapidly increasing pharmacy cost within the STVHCS. Defining this problem required a good overview of what has been happening with cost, and the factors that contribute to this cost, over the last several years. Table 1 shows the total pharmacy spending (less salaries) and per cent of total operating budget for ALMMVH and associated satellite clinics for FY90 to FY94. Total expenditures have risen over the

period, with an apparent peak in supply expenditures in FY92. Pharmacy managers anticipate that FY95 spending will exceed that of FY92. The proportion that pharmacy cost contributes to operating cost was up only slightly over the period, again with a peak in FY92. These data appear to indicate that the system did not experience an uncontrolled expansion of pharmacy cost as first thought.

Table 1. Total Pharmacy Cost for ALMMVH, FY90-FY94

Fiscal Year Budget	Total Pharmacy Cost	% ALMMVH Op.
FY90	$8,532,500	7.2%
FY91	$10,714,000	8.27%
FY92	$12,692,000	8.85%
FY93	$11,889,500	7.87%
FY94	$12,442,000	7.61%

Further analysis requires the recognition that total pharmacy expenditures are actually made up of two major pharmacy activities - inpatient pharmacy (for which a main cost driver is patient-days), and outpatient pharmacy (for which a main cost driver is patient visits). According to the FY94 Pharmacy Resource Utilization Indicators report published by the DVA, ALMMVH inpatient pharmacy cost per patient day ($20.98) just exceeded the median cost ($19.69) and mean cost ($19.50) for all the major VA medical centers throughout the United States. Comparing pharmacy cost per outpatient (unique

SSN) among the same group reveals that ALMMVH average cost per outpatient ($244.54) again was only slightly above the median rate ($226.86) and the mean rate ($221.55). Once again, even though both inpatient and outpatient pharmacy expenditures may be deemed excessive by local managers, they do not appear to be very much different from the spending rates experienced by like facilities.

Figure 1 shows the inpatient pharmacy cost per patient day experienced by the hospital during the ten quarters beginning 1 October, 1992. These cost figures were transcribed from an automated monthly report reflecting the cost of pharmaceuticals actually sent to the wards either for specific patients or for ward stockage. With the exception of the second quarter FY93, when total cost remain constant but reported patient census was less than half the mean, and fourth quarter FY94, when cost of intravenous preparations more than doubled, inpatient cost remained relatively stable. More in-depth analysis of the cost on a ward-by-ward basis failed to reveal any striking trends.

Figure 1. Inpatient Pharmacy Cost - ALMMVH

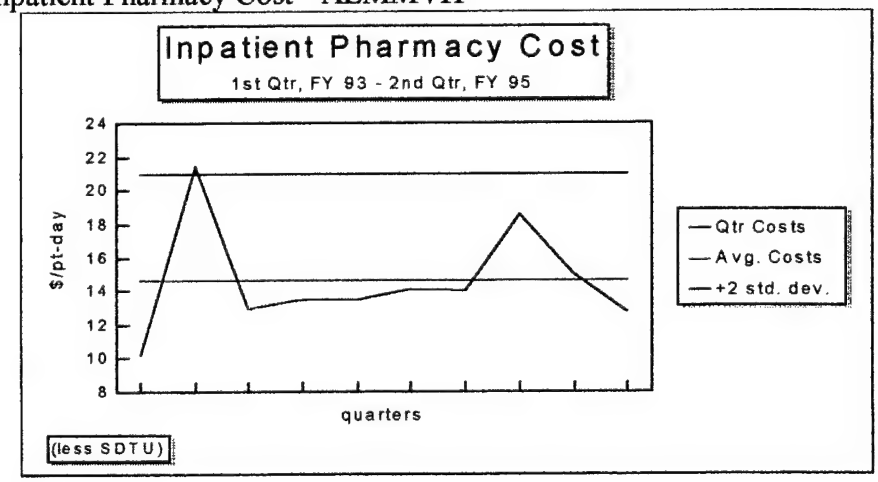


Figure 2 shows the monthly outpatient pharmacy cost for the 33 months beginning 1 October, 1992. This graph shows a fairly consistent increase in outpatient pharmacy expenditures of 1.4% per month. Figure 3 shows the monthly cost, visits and prescriptions indexed to the base month, October 1992. Similarly, Figure 4 shows cost per visit, prescriptions per visit and cost per prescription indexed to the same base month.

Figure 2. Outpatient Pharmacy Cost - ALMMVH

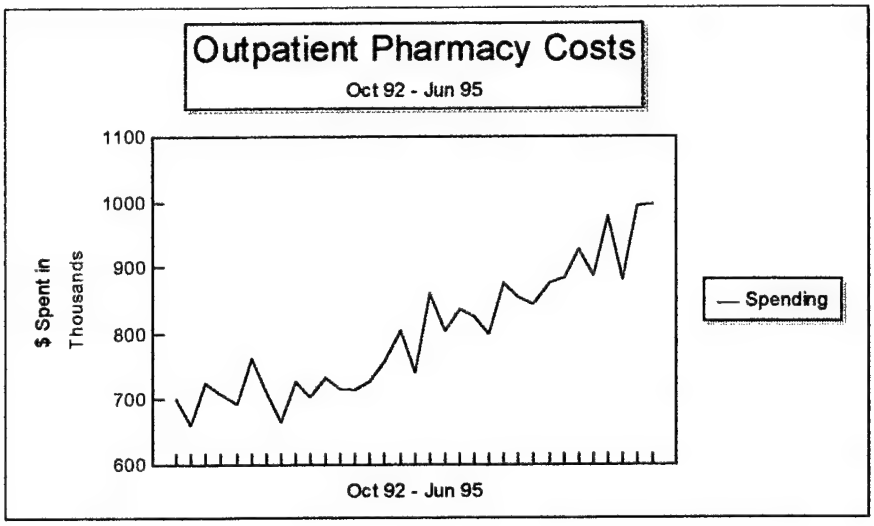


Figure 3. Outpatient Pharmacy Indexed Profile

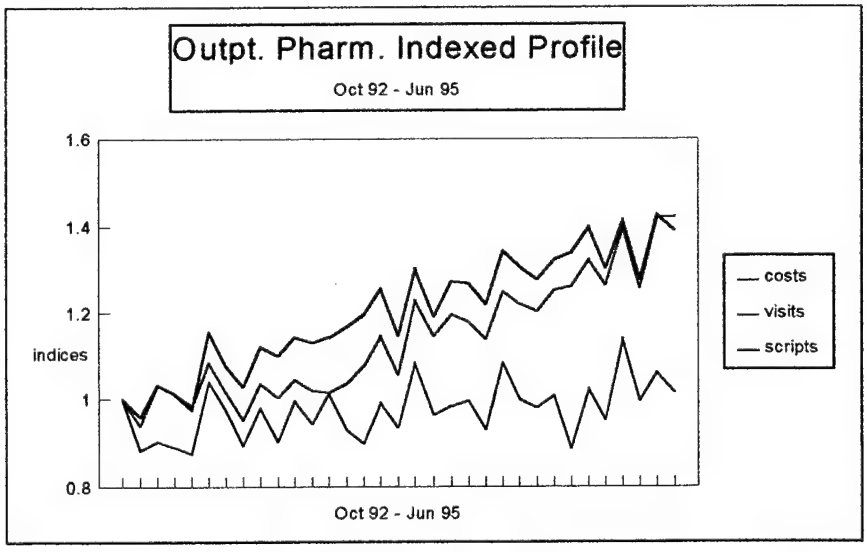
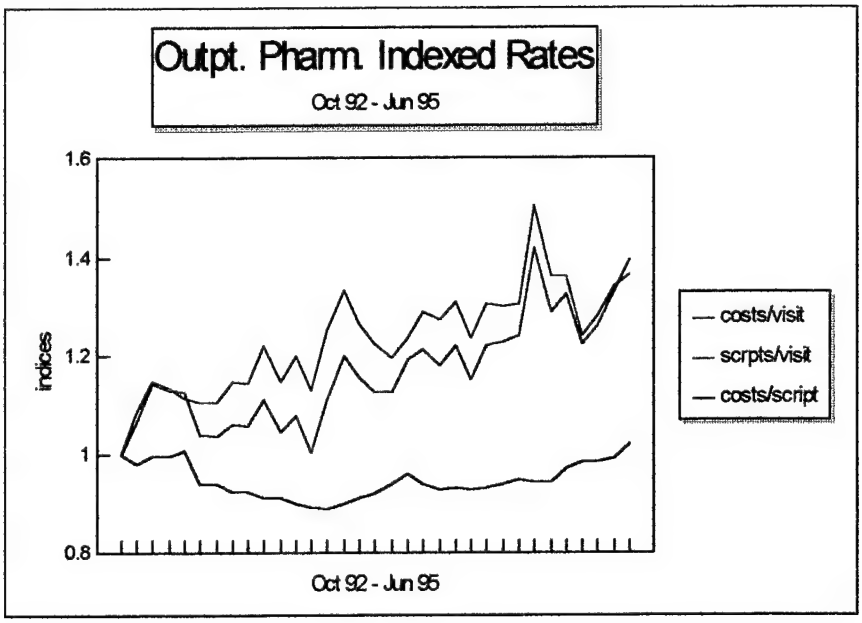


Figure 4. Outpatient Pharmacy Indexed Rates



A model was developed whereby total cost is the product of the three factors: average cost per prescription, average number of prescriptions per visit, and number of visits per month. Analysis of these factors shows that, over the 33 month period, average cost per prescription and number of visits per month increased by only 0.04% and 0.3% per month, respectively, while the average number of prescriptions filled per outpatient visit rose consistently by 0.9% per month. Thus, the primary contributor to increasing outpatient cost was the number of prescriptions patients receive per outpatient visit. These findings are supported by the independent findings of another administrative resident who demonstrated a system-wide 29% increase in number of prescription items per outpatient over a three year period (FY92-FY94). Numbers of individual patients and outpatient visits only increased by less than 1% and less than 2%, respectively, over this same period.

Analysis Summary

Conclusion 1. Pharmacy cost at ALMMVH and associated clinics have not increased over the last several years as a percent of the operating budget.

Conclusion 2. Both inpatient and outpatient pharmacy cost, whether viewed on a per patient-day or per patient visit basis, were only slightly higher than those experienced by other similar VA medical centers during 1994.

Conclusion 3. Inpatient pharmacy cost, while showing considerable quarterly variation, has been, on the average, relatively stable over the past ten quarters.

Conclusion 4. Outpatient pharmacy cost rose a fairly consistent 1.4% per month from October 1992 to June 1995. Almost two-thirds of this increase is accounted for by a corresponding 0.9% monthly increase in the number of prescriptions per outpatient visit over the same time period.

Discussion

While the above analyses do not demonstrate a clear "problem" with out-of-control cost, they do indicate that spending associated with outpatient pharmacy is growing at a rate higher than normal inflation (recently, 4% for budgetary purposes). This growth is apparently due to veterans receiving an ever-increasing number of prescriptions. One can speculate as to why this growth is occurring.

The clinical staff seems to believe that as the veterans age they are generally sicker and require more medications. Similarly, as the art of medicine advances, more medications are available to provide long-term therapy to these sicker veterans (Stuart & Coulson 1993, Chrischilles 1988). Both of these seem to be long-term phenomena that

should not impact on short-term cost, at least not at the rate of a 10% increase in medications prescribed per year. Another clinically-oriented hypothesis concerns the shift from inpatient, specialty care to outpatient, primary care. More patients now seen as outpatients are likely to be sicker and might require more medications than before this shift. As these sicker patients receive more prescription items on a per patient basis, unless there is a corresponding increase in the number of visits, the rate of prescriptions per visit will also increase.

The pharmacy staff takes a very different view from that of the clinicians. One group of pharmacists believe that the cost increases are due to over-prescribing on the part of the clinical staff. Another group believes the increase in prescriptions is a reflection of non-specialists' reluctance to discontinue medications that a specialist has ordered. Thus, every time a patient is seen as an outpatient, not only are new medications added, but all old medications are renewed. If this were the case, one would expect that veterans are receiving medications they no longer need.

Determining the reasons for the continuing prescribing rate increase would require in-depth research. It seems likely that the findings would show myriad reasons for the increase. Inappropriate or over-prescribing probably play some part in the increased cost. If this is indeed the case, a program designed to bring to the attention of clinicians specific prescription items that can be eliminated, reduced, or changed to less expensive alternatives should result in reduced pharmacy cost. To the extent that such a program identified inappropriate therapy and reduced the risk of adverse outcomes, such as drug-drug interactions, the quality of care provided would also be improved.

Study Question

The study question for this GMP is this: Can a program designed to uncover inappropriate and unnecessary prescriptions through clinical pharmacist case review reduce outpatient pharmacy expenditures sufficiently to pay for itself?

Literature Review

The relevant literature for this project includes several areas: trends in the use of pharmaceuticals among aging populations, pharmacoeconomic study design, the role of Drug Utilization Review (DUR) programs in controlling pharmacy cost, the role of clinical pharmacy in controlling pharmacy cost, and the potential impact of a learning curve on reviewer efficiency.

Trends in the use of pharmaceuticals among the elderly.

According to Stuart and Coulson, between 1980 and 1987, per capita spending by the elderly on outpatient prescription drugs grew by more than 14% per year, representing one of fastest growing components of spending in health care - cost increases very similar to those experienced by ALMMVH during FY93 through FY95. Focusing specifically on social insurance, they identified several factors that would be expected to produce increasing levels of use (*i.e.* pharmacological advances and new drug therapies, population aging, beneficiary adaptation to insurance coverage, disenrollment of low users), but stated that those factors should be countered by factors having an opposite effect (enrollment growth representing new inexperienced users and deaths). They did identify two factors contributing to ever-increasing pharmacy cost and

drug utilization in their study group: increasing patient age and increasing patient experience with the system (Stuart & Coulson 1993).

Both factors are present within the VA. According to Inglehart, although there has been a steady influx of young veterans into the system throughout the years, the large peaks of World War II and Korean War veterans have a major impact on the age distribution of the veteran population. In 1980, only 10.5% of those served by the VA were over 65 years of age. This figure was projected to increase steadily to 26.6% and 37% of the beneficiaries in the years 1990 and 2000, respectively (Inglehart 1985). According to recent VA "Distribution Population Planning Base (DPPB)" reports, the number of veterans older than 75 years of age living within the STVHCS region will increase from 35,000 in 1993 to over 71,000 in 2000. Obviously, most of these older veterans have had up to fifty years' experience with the VA system.

Purves and Edwards also studied pharmacy utilization and cost trends. However, they compared these rates indexed by different age categories and sex. They reported that both the cost per prescription and number of prescriptions per year rose with age. For males, the average number of prescription items used rose from approximately 5.7 per year at age 50, to 10.6 items per year at age 60, to 18.4 items per year at age 70. As expected, the average pharmacy cost for each age group also rose from 49£ per year, to 89£ per year, to 127£ per year, respectively. (Purves & Edwards 1993)

This portion of the review clearly indicates the STVHCS is not alone in experiencing increasing number of prescription items per patient or increasing pharmacy costs. However, because of the ecological nature of the data presented, one cannot

conclude that individual patients require more medications merely due to increasing age. If this were the case, because the aging process cannot be controlled, neither could increasing pharmacy costs.

Pharmacoeconomic study design.

This project is classified as a pharmacoeconomic study. Jolicoeur *et. al.* published a useful article describing the different methods of pharmacoeconomic analyses and the steps an investigator should take in designing a study. Five types of analyses were described: cost-minimization, cost-benefit, cost-effectiveness, cost-utility, and quality-of-life. This project is of the cost-minimization type. Although most pharmacoeconomic analyses are oriented toward examining the use of specific drugs and therapeutic regimens, as opposed to a cost-containment program, the recommended steps for designing the analyses appear to be applicable. The authors described ten steps to study design, to include: define problem, determine study perspective, determine alternatives and outcomes, select appropriate study type, place monetary value on outcomes, identify resources, establish probabilities of outcome events, use decision analysis, discount cost or perform sensitivity analysis, present results. (Jolicoeur *et. al.* 1992)

Drug Utilization Review (DUR) programs.

During the recent past, there appears to have been a fairly broad spectrum of efforts to control pharmacy cost. At one end of this spectrum lies the DUR program. Generally speaking, DUR programs are population-based, and oriented toward comparing health care providers' prescribing patterns with predetermined standards. In

1976, Brodie & Smith described the conceptual basis for DUR programs, the purposes of which were defined as cost-avoidance and improved quality. When used in a general sense, DUR means local, short-term, free-standing drug use studies. When used to describe specific efforts, DUR refers to applying the principles of utilization review and management to the drug component of health care; *i.e.*, a structured program where drug use is measured against predetermined standards. (Brodie & Smith 1976)

Kralewski, Wertheimer & Ratner provided a much more complete examination of DUR. They defined DUR as those programs designed to control improper prescribing and dispensing patterns among physicians and pharmacists. These authors described five levels of review:

level 1 - ***contract compliance*** - oriented toward controlling prices, volume, and formulary.

level 2 - ***fraud and abuse*** - oriented toward assuring proper billing, the patient getting what was prescribed, and controlling inappropriate drug use and hoarding, and duplicate prescriptions.

level 3 - ***drug-centered screens*** -programmatically reducing drug/drug incompatibilities, inappropriate use of drugs, and use of high-cost drugs.

level 4 - ***patient drug profile reviews*** - creating patient profiles and looking out for drug incompatibility, wrong dose, wrong dose for diagnosis, drug-induced illness, overuse of drugs, hoarding.

level 5 - ***patient therapeutic program reviews*** -creating patient drug profiles linked to diagnostic data and providing for peer reviews of profiles with follow-up reviews of individual physicians' practices. (Kralewski, Wertheimer & Ratner 1994)

In reviewing several DUR programs Kralewski *et. al.* made several useful observations. For one program, the patients in the top quartile of the drug cost or volume distributions and/or those that used more than two pharmacies for their prescriptions had a 60% chance of having at least one prescription drug problem. Of 13 categories of problems, those related to drug overuse (multiple prescriptions for same drug, refill abuse, excessive volume dispensed for condition, and the wrong dosage of maintenance drugs) accounted for 60% of the problems. Another 29% of identified problems were related to non-use of generics, or failure to select less expensive alternatives. The authors reported that approximately 6% of studied populations had an identifiable pharmacy problem and that the DUR process saved approximately 1% of pharmacy cost. Average cost-effectiveness estimates realized were $4 saving for every $1 spent. One particular program reviewed merely included emphasizing generic drug use, mandating certain pharmaceutical brands, identifying multiple prescriptions for same or similar drugs, and educating providers of lower cost alternatives. Yet, this program still resulted in $2.80 saved per $1 spent. The authors concluded that even the higher cost programs were cost-effective. (Kralewski, Wertheimer & Ratner 1994)

Role of clinical pharmacist in controlling pharmacy cost.

At the other end of the pharmacy cost-containment spectrum are those efforts involving clinical pharmacists. In 1989, Willett, *et. al.* published the results of an extensive literature review and listed published studies, to date, that concerned the economic value of clinical pharmacy services. They found that the vast majority of studies concerned the cost-benefit, cost-effectiveness, or cost-utility of specific

alterations in specified therapeutic regimens. Those studies that involved several primary care sites appeared to examine the cost-avoidance and quality improvement experienced when a clinical pharmacist participated as a physician extender in a specific clinical setting. Few of the studies listed appeared to contribute significantly to the issues at hand. (Willett *et. al.* 1989)

Carter and Heilling described the role of clinical pharmacy in the primary care/ambulatory setting. In many cases, the clinical pharmacist served as a physician extender and was privileged to write prescriptions for patients with certain diagnoses (e.g., hypertension). At other clinics, the clinical pharmacist served as a consultant and patient educator. These authors cited two studies where 96% of the clinical pharmacists' recommendations were implemented; however, they made no statement regarding pharmacy cost savings realized by this level of implementation. The authors did conclude that the efforts of a clinical pharmacist were cost-effective, but did so in terms of avoided hospitalizations and poor outcomes, and improved patient care and perception of quality. (Carter & Heilling 92)

Hatoum *et. al.* measured cost avoidance produced by inpatient pharmacy profile review by clinical pharmacists. They found that a pharmacist was able to make approximately 3.2 recommendations per day and that each recommendation resulted in an average cost-avoidance of $242. On average, only 10.2% of the recommendations were ignored by physicians. After discounting for cost of clinical pharmacy personnel, this program resulted in a projected annual savings of $365,000. These authors provided a list of drug therapy inappropriateness categories (bases for recommendations) similar to

that used by other investigators. Problems included: no clinical indication, drug not given when clinically indicated, not the safest or most effective medication, duplication, less costly drug available, contraindication, conflicting medical regimen, and inappropriate dose. (Hatoum et. al. 1988)

In their study of pharmacy profile use, Chrischilles *et. al.* found that only 21% of reviewed records had accurate documentation of all drug names, drug strengths, and directions. Furthermore, there was evidence of potential inappropriate prescribing present in 43.4% of patient pharmacy profiles, and the probability of a problem being detected by the pharmacist increased with number of prescription items. These authors found that a patient might not be currently taking all technically active medications listed in his or her profile. For example, drug therapy may have been discontinued by the prescriber without notification of the pharmacy, or the patient may have stopped taking the drug without informing the physician. While this article did discuss the efficacy of retrospective pharmacy profile and medical record review in an outpatient setting, no analysis of the cost savings potentially realized by such a program was reported. (Chrischilles *et. al.* 1988) In a similar effort, Tamai *et. al.* found that, in a General Medicine clinic, computerized pharmacy profile review and clinical pharmacist consultation resulted in a reduction in the number of medications and drug-therapy problems. Once again, this study was oriented primarily towards quality improvement and the report provided no cost-effectiveness analysis. (Tamai *et. al.* 1987)

Finally, Mason and Colley reported on a study very similar to the one proposed here. However, the pharmacist review took place just prior to the patient visit and results

for the study clinic were compared to physician-initiated pharmacy profile changes taking place in a clinic without clinical pharmacist participation. For the 300 patient pharmacy profiles reviewed, 122 had at least one recommended change. These authors reported that the primary problems identified were therapeutic duplication, inappropriate indications, and patient noncompliance. For this study, only 50% of the recommended changes were actually implemented by the physicians. However, even with this relatively low implementation rate, the program would have resulted in the savings of $176,000 per year - four times the salary cost of the clinical pharmacist. (Mason & Colley 1993)

This portion of the literature review yielded several useful pieces of information. The 96% implementation rate observed by Carter and Heilling was the highest rate found; therefore, this rate was used to represent the "best case" for this project (Carter & Heilling 1992). Likewise, the 50% compliance rate reported by Mason and Colley was the lowest rate observed; a 50% compliance rate was the basis for "worst case" implementation. Additionally, several of the articles reported methods for classifying the bases for recommended changes in prescriptions. While these actual lists may not be directly applicable, they do serve as a starting point for this project.

CHAPTER 2

METHODS AND PROCEDURES

Project Overview

The purpose of this project was to test the effectiveness (in terms of cost-minimization) of clinical pharmacy case management for outpatients within the STVHCS. The pharmacy records for three patient samples were reviewed independently. A random sample of patients from the San Antonio (SAOPC) and Audie Murphy (ALMOPC) outpatient clinics, as well as a sample of patients who receive more than nine separate prescription items from the system on an ongoing basis (polypharm group), comprised the samples. Pharmacy profiles and outpatient records were reviewed by either a clinical pharmacist holding a doctoral degree in pharmacy, or a staff pharmacist holding a bachelor's degree. The pharmacists made recommendations regarding beneficial changes in specific prescription items. Changes in cost were determined by calculating the differences in cost if no changes were to be made in specific prescriptions from the cost associated with implementation of all recommended changes. Assuming there would be some cost savings associated with the pharmacists' review, the potential financial benefits of implementing this program for each of the three settings were determined by comparing cost avoidance with the corresponding personnel cost of

implementing a notional pharmacy case review program. Although final recommendations to management were to be based primarily on the financial outcome of this study, the potential quality improvement aspects of the pharmacy case management efforts were also reviewed.

Reviewing Pharmacists

Dr. Marv Amato.

Dr. Amato was the clinical pharmacist reviewer for this project. Dr. Amato earned her Pharm. D. degree from the University of Texas in 1987. She also completed graduate work in public health and post-doctoral training in ambulatory care clinical pharmacy. From 1992-95, Dr. Amato served as an ambulatory care clinical pharmacy specialist for the Bexar County Hospital District, where among her duties was the review of pharmacy profiles for outpatients. Since March 1995, Dr. Amato has served as a clinical pharmacist for ALMMVH Extended Care Treatment Center, performing ongoing drug regimen reviews for extended care patients and monitoring drug therapy of outpatients in the Therapeutic Drug Monitoring Clinic.

Dr. Amato completed the review of approximately 100 records from each of the three samples.

Ms. Melissa Quezada.

Ms. Melissa Quezada is a staff pharmacist holding a Bachelor's degree in Pharmacy from the University of Texas at Austin since 1983. Ms. Quezada spent six years working as a retail pharmacist. For the last five years, she has worked in the

Outpatient Pharmacy at ALMMVH as a staff pharmacist. In April, 1995, Ms. Quezada transferred to the Evaluation Unit (General Outpatient Medicine/Acute Minor Illness/Emergency Medicine) where she fills the traditional role of a clinical pharmacist. In this role, Ms. Quezada works closely with both patients and clinicians, monitoring pharmacy profiles and providing education.

Because of her normal work schedule, Ms. Quezada was only able to participate in reviewing 91 records from her portion of the ALMOPC sample.

Reliability and Validity

Prescription Data.

Every time a prescription is filled by one of the STVHCS outpatient pharmacies, the automated pharmacy profile for the veteran receiving the prescription is updated. Data on this profile include all active medications, all prescriptions filled by the pharmacy over the previous 45 days, refills remaining for each item, and the associated supply cost for each item. These data are assumed to be both reliable and valid in that every time pharmaceutical supplies are received by pharmacy from vendors, an itemized invoice and price list is also received. A technician spends approximately two hours each morning updating the pharmacy database. Thus, the medication price on the pharmacy profile reflects the most recent direct supply cost of that item to the STVHCS.

Outpatient medical records are probably not equally reliable. Patients are not required to have every prescription filled within the system. Likewise, although the pharmacy only fills prescriptions written by VA physicians, there is no assurance that a

notation is made in the record every time a prescription is written, especially in those cases where a VA physician is rewriting a prescription for a non-VA provider. In all cases where there is disagreement between the outpatient medical record and the pharmacy profile, the pharmacy profile data will be used. In fact, one major reason for a reviewing pharmacist to recommend discontinuing a medication may well have been the lack of clinical indication in the outpatient record.

Pharmacists Review.

Both participating pharmacists had considerable experience reviewing patient pharmacy profiles. They are both, therefore, considered to be "experts." However, because their educational backgrounds and experiences are different, it seemed likely that specific recommendations and reasons for those recommendations would be different. To confirm and document the reliability of judgments of the experts, approximately 10% of the records were to be reviewed by both pharmacists. The pharmacists were not to be aware of which records were being reviewed by both. Following this review, the changes (and reasons for the changes) recommended by each were to be analyzed and the degree of agreement determined. Unfortunately, because Ms. Quezada was unable to participate in the full review, this redundant review was not accomplished.

Ethical Considerations

Patient Privacy.

Each of the participants in this project possessed appropriate clinical privileges within the STVHCS and, therefore, enjoyed full access to patient medical records. The patients' last names and last four digits of the Social Security Numbers, were used only to join the individual's medical record and pharmacy profile. For this project, the only demographic information recorded was age and sex.

Clinical Impact.

Case management recommendations had no direct impact on patient care. During the course of the project, the patient's primary care physicians were not notified normally that a patient's record was part of this project, nor that recommendations to change the pharmacy profile had been made. However, the treating physician was to be notified immediately for any case that the reviewer detects that a patient's health might be adversely impacted by the prescribed drugs (e.g. drug/drug interaction). Had this occurred, the treating physician maintained sole authority to alter patient treatment. Upon the completion of the project, the actual recommendations were given to the STVHCS Chief of Staff for his consideration.

Sample Size

Originally, each of the three groups was to consist of a minimum of 200 randomly selected patient records. This sample size was arrived at using the following reasoning:

Assumption 1. Based on their experience, the reviewing pharmacists estimated that reviewing each record would require between 15 and 30 minutes. At these rates, a pharmacist assigned the task of reviewing records for four hours each day would be able to review between 150 and 300 records each month. Thus, 200 records approximates a reviewing pharmacist's monthly workload. If this were indeed a cost effective program, significant savings would be readily discernible using a sample size of 200.

Assumption 2. Each of the three samples were likely to have different rates of recommendations. For the polypharm group, up to one of every two records reviewed might result in some type of cost saving recommendation. For the ALMOPC group, where a large percentage of the sample was likely to have specialty referrals, house staff providers, and no designated primary care provider, this ratio was assumed to drop to as low as 1 in 4 records. For those patients from the SAOPC sample, where continuity of care is easier and illness acuity is, on the average, less severe, the ratio was assumed to be down to 1 in 10 records. If the reviewing pharmacist were to make only one cost saving recommendation every 10 records, 200 records reviewed would result in only 20 recommendations. If these recommendations resulted in an assumed average savings of $50 each, the total savings they would represent would be $1000. If 200 records represent 1/2 of the average monthly work of a reviewing pharmacist, total monthly savings represented are $2000, or very near the break even point (staff pharmacist's salary). Because most recommendations would result in more than one month's savings, and because records resulting in such a low ratio of recommended savings are likely to be very simple, and thus, very quick to review, even for the least cost-efficient of the three

settings, 200 records should be adequate to detect significant savings, if they were present.

Assumption 3. Although the primary focus for the project was cost-minimization analysis, if sufficient numbers of recommended changes were generated, further descriptive analysis stratifying by reason for recommendation, class of drug being affected, patient characteristics (age and sex), and reviewer making the recommendation would be possible. The statistical power to stratify the outcome measures was dependent on the number of recommended changes. On one hand, only 20 recommended changes for one of the groups would severely limit how many ways outcomes could be subdivided. On the other hand, if fewer than 20 recommended changes were made for 200 records reviewed, there would be little reason for further analysis, as that portion of the program would unlikely be cost-effective.

Project Steps

As originally conceived, the project was to be conducted in four major steps. Step 1 would consist of the investigator selecting the three samples and generating the pharmacy profiles from the computer system. Step 2 would be the actual record review by the two reviewing pharmacists. Step 3 would be calculation of the pharmacy cost avoided for each sample. Step 4 would be calculating the cost of labor associated with review process for each sample. Step 5 would be the actual cost-minimization analysis. In actual practice, only Steps 1 and 2 were altered significantly.

Step 1: Selection of Samples.

The three samples were selected from the appropriate populations by matching the last number(s) of patients' SSNs with a random one or two digit number. Digit matches were conducted until the sample size exceeded 200 individual patient records. It was originally planned that the pharmacy database manager would print the pharmacy profiles for each patient in the sample. The reviewers were to be assigned every other patient and approximately every tenth profile generated would be assigned to both.

In actual practice, while the samples were generated as described, the reviewers were given only a list of patient names and SSNs. The reviewers had found it very easy to screen patient pharmacy profiles using the computer terminal. From this initial screening, patients could be divided into two categories: Category A - no recommendations, no further review required; and, Category B/C - possible recommendations, the "Informational Prescription Profile" hardcopy required.

Additionally, only Dr. Amato was actually given all three samples. When it became obvious that Ms. Quezada would not have sufficient time available to complete all three samples, she was asked to complete review of the ALMOPC sample only.

Step 2: Record Review.

The pharmacy profiles were to be provided to the reviewing pharmacists who would use the profile as their data sheet. It was assumed that the outpatient medical record would not be required for all records; however, when a record was requested, the investigator would personally pull the record, noting the labor time for costing purposes. On the data sheet, the pharmacist was to note any recommended prescription changes,

the reason for the change, date/time of the review, and the total time required to review the profile and, if applicable, the medical record.

The actual review process was to take place as follows:

- The investigator would provide each pharmacist at least 100 profiles to review.

- The pharmacist would be asked to set aside blocks of time of at least two hours each to conduct the initial review. During this block of time, the reviewer was not to participate in other professional activities. However, brief, recurring distractions (*e.g.* pouring a cup of coffee) are a normal part of the workplace; the reviewing pharmacists were asked not to eliminate or record these non-productive activities.

- The reviewer was to note on each reviewed profile one of the following: Category A - no recommendations; Category B - pull record to confirm recommendations; or, Category C - pull record for further in-depth review.

- The reviewer would return to the investigator all profiles reviewed during a block of time and report the duration of that block (*e.g.* the reviewer would submit ten profiles and report that they were reviewed in a 2-hour block).

- Category B and C records would be grouped separately and each group would be reviewed during separate time blocks. Upon final review, the reviewer would again note the duration of time required to review the records (*e.g.* ten Category B, four hours; six Category C, four hours).

Upon completion of the review process, each reviewer was to participate in a consultation with a physician selected by the investigator to simulate the implementation/confirmation process. Because Category B and C records were assumed

to be of different complexity, they would be reviewed during separate consultation sessions. The duration of each of these sessions would be recorded for analysis and costing of labor.

Although both reviewers had had considerable experience reviewing pharmacy profiles and developing treatment plans, neither had participated in a case review process. Therefore, it was anticipated that the reviewers would learn to review records more efficiently as the study progressed. The review rates and the quality of recommendations experienced during the latter part of the study should better reflect rates and quality for an ongoing program (Gleim & Flesher 1994). To compensate for learning efficiency, the time involved for each profile and record review were be recorded. Should the review and recommendation rates for the last quintile of records reviewed differ significantly from the first quintile, the last quintile rates would be used in lieu of average rates.

In actual practice, Step 2 was altered significantly during the actual review process as follows:

Dr. Amato's review process.

- Upon receiving the sample, Dr. Amato quickly reviewed the on-line pharmacy profile for each patient. From this initial screening, patients were divided into two categories: Category A - no recommendations, no further review required; and, Category B/C - possible recommendations, the "Informational Prescription Profile" hardcopy required.

- Next, Dr. Amato reviewed the hardcopy pharmacy profile, and determined two things. First, she was able to determine what recommended changes she had for each patient's prescription items and why. Second, she was able to determine which patients' medical record required review in order to confirm the validity of the recommendations. From this level of screening, patients were further divided into: Category B - with or without recommendations; no further review necessary, and Category C - medical record review necessary to confirm the recommendations.

- Dr. Amato was able to set aside sufficient time to complete the first two levels of screening in a single session for each sample.

- The investigator then pulled the required medical records. In the case of SAOPC and ALMOPC, Dr. Amato was able to complete the medical record review in a single session for each sample. In the case of the polypharm group, many of the records were not immediately available, and they were provided to Dr. Amato in groups of ten to twenty.

- The original intent was to have Dr. Amato review her recommended changes for the SAOPC and ALMMVH samples with the Chief , SAOPC and Chief of Staff, STVHCS, respectively. Because of repeated scheduling conflicts, only the consultation session with the Chief, SAOPC actually took place.

Ms Quezada'a review process.

Due to the demands of her normal work schedule, Ms. Quezada was unable to set aside specific blocks of time to conduct the review. Therefore, she altered her review methods to allow for review of the pharmacy profiles in the times that became available

during the normal workday. Instead of conducting step-wise screening on the entire sample, Ms. Quezada elected to complete one patient at a time. Thus, she would review the on-line pharmacy profile, categorize the patient into Category A, B, or C, and retrieve, personally, and review the medical record for the Category Cs.

Step 3: Cost-Avoidance Calculations.

The primary dependent outcome measure for this project was "cost-avoidance (incurrance)". The information management system contains the by-item cost for each item dispensed by a STVHCS pharmacy. These data include non-formulary item cost. These cost data are published on the pharmacy profile for individual patients.

At the time this project was conducted, approximately 67% of all prescriptions were processed through the mail by a contractor in Dallas (Centralized Mail-out Pharmacy, or CMOP). The CMOP contractor bills the STVHCS for each prescription refilled on a month-by-month basis. In addition to direct supply cost, the CMOP contract adds an administrative overhead charge ($.40 per prescription), a labor charge ($.80 per prescription), and a mailing charge ($.60 prescription). Because the marginal cost of refills processed by a STVHCS pharmacy was not available, the per prescription charges imposed by the CMOP ($1.80 per prescription) were considered the cost avoided for all canceled prescription items.

Every prescription filled (even those prescriptions filled by the CMOP), require several minutes processing time on the part of the STVHCS Pharmacy Service. Likewise, every prescription changed or canceled requires processing time. Because the

cost of labor associated with processing a refill and processing a change were deemed to be roughly equivalent, this aspect of labor cost was not included in the calculations.

Staff pharmacists report that often when a physician cancels a medication that a patient is expecting to have refilled, the patient calls the pharmacy to find out why he did not receive all medications. The pharmacists reached a consensus that on the average these queries (complaints) require ten minutes of a GS11 pharmacist's time ($20 per hour) to address. This cost will be added once for each recommended change in medications.

In calculating the cost associated with each recommendation each patient served as his own control, *i.e.* the cost of pharmaceuticals, assuming no changes, were compared to the cost associated with the pharmaceuticals assuming that all recommended changes were implemented. Cost differences were projected for three time periods: monthly differences, total differences for the remaining life of the changed prescription, and total differences assuming that when the currently written refills were used, the prescription would be automatically renewed for one year.

For example, if Mr. Smith was found to have four 60-day refills for the non-steroidal anti-inflammatory drug (NSAID) ibuprofen and three 90-day refills for the NSAID, aspirin, the reviewing pharmacist might recommend discontinuing the more expensive ibuprofen. Table 2 represents the calculations for the cost avoided by canceling the ibuprofen prescription ($.09 per day).

Table 2. Sample cost avoidance calculation.

	Monthly Cost	Refills	Prescription Cost	Additional Year
Direct Supply	$2.70	4	$10.80	$43.20
CMOP Cost			$7.20	$28.80
Phone Consultation			($5.00)	($5.00)
Cost Avoided			$13.00	$67.00

Treating physicians are unlikely to implement all of the recommended changes. Thus, in a real-world program, some of the calculated savings would never be realized. To compensate for less than perfect implementation, two savings results are reported: worst case (savings adjusted for the lowest compliance rates found in the literature [50% - Mason & Colley 1993] reduced by 10% of that rate to be conservative, producing a implementation rate of 45%), and best case (potential savings adjusted for the highest implementation rates found in the literature [96% - Carter & Heilling 1992]).

Step 4: Cost of Labor Calculations.

While Step 3 resulted in the cost avoidance or incurrance of the review process based on the recommended prescription changes, Step 4 produced the labor cost associated with the process of reviewing the records and communicating the recommended changes to the clinicians. The only cost identified as incremental due to the project was labor.

The primary labor cost was the pharmacist review time. The pharmacists recorded all time spent working on the various review activities for each of the three sample. This total time, in hours, was then multiplied by the hourly pay and benefits rate for a GS-13, Step 5 employee.

For example, if Dr. Amato were to have completed her review of the 123 SAOPC records in the equivalent of one 4-hour pharmacy profile review block, one 5-hour record review block, and two 1-hour consultation blocks, and her hourly labor (salary and benefits) was $37 per hour, then the cost associated with review of the sample would be reported as a total of approximately 11 hours times $37, or approximately $407.

Another labor component associated with the review program would be the time spent by physicians reviewing and implementing changes during the consultation blocks. Therefore, based on a physician's salary and benefits of $83 per hour (according to Chief, Fiscal Services, STVHCS), the physician's labor cost for the example would be $166 (two 1-hour consultation blocks).

The final labor cost to be included was that incurred when a GS5 personnel clerk ($13.25 per hour) pulled medical records. In the above example, 50 of the reviewed pharmacy profiles might have required record review. Based on the three hours required when the investigator pulled 60 SAOPC records for review, each record is assumed to require approximately three minutes to be pulled. Thus, another $33.60 labor cost would be added.

Step 5: Analysis of Cost-Minimization.

For the cost-minimization analyses, the calculated cost avoided for each sample (potential, best, and worst cases) were compared to the corresponding labor cost increased. These ratios and the actual differences were calculated.

Additionally, to correct for different sample sizes and to make projections regarding probable outcomes should this type of review activity be applied to STVHCS

Table 3. Sample calculation of total labor cost.

	Hours	$ per hour	Activity Cost
Pharmacist:			
Profile Review	4	$37.00	$148.00
Record Review	5	$37.00	$185.00
Consultation	2	$37.00	$74.00
Physician:	2	$83.00	$166.00
Record Clerk:	2.5	$13.25	$33.60
Total Labor Cost for Sample:			$606.60

patients, the following rates were calculated: number of recommendations per 100 records, average cost avoided per recommendation, and number of hours required to complete 100 records. Denominator data representing the outpatient populations for the ALMMVH, the Kerrville Division, and the five outpatient clinics were obtained from the

Medical Administration Service. Additionally, the Pharmacy Service provided a computer printout of all patients within the system with ten or more active prescriptions as of 11 October, 1995. Because the ALMOPC patients are cared for within a tertiary care center, calculated rates for the ALMOPC sample were applied to the ALMMVH population. Calculated rates for the SAOPC sample were applied to the Kerrville Division and five outpatient clinics. Thus, potential "best case" and "worst case" program savings, and the labor cost associated with those savings were projected for the STVHCS.

CHAPTER 3

FINDINGS

Pharmacist Review Results

The results of the pharmacist review are presented for four separate samples: ALMOPC (Dr. Amato), SAOPC (Dr. Amato), PolyPharm (Dr. Amato), and Staff Pharm. (Ms. Quezada). The target sample size was to be 100 for each sample and each reviewer. As given to the pharmacists, the original sample sizes exceeded the target. However, most of the PolyPharm group required medical record review and only one-third of the records requested were available at any given time; thus, only 57 unique patients comprised the sample. Because recommendation rates appeared to be dependent on the number of prescriptions in the sample, rather than the number of patients, attempts to obtain additional medical records were abandoned when the number of prescriptions in the PolyPharm sample exceeded 600. In the case of the Staff Pharm. sample, Ms. Quezada was only able to completely review 91 records. Table 4 summarizes the results of the pharmacists review in terms of sample size, distribution of records among categories, number of prescriptions represented in the sample, number of recommendations generated for the sample, and total number of refills represented by the recommendations. Here, category A refers to those sample members which were

eliminated from further review during initial screening; category B were those for which the hardcopy pharmacy profile screening was sufficient; and, category C were those which required medical record review.

Table 4. Review Results Summary.

	Records:	As	Bs	Cs	Prescriptions:	Recommend-ations:	Refills Affected:
ALMOPC	109	21	28	60	606	117	574
SAOPC	123	33	30	60	609	117	593
PolyPharm	57	0	12	45	690	152	632
Staff Pharm.	91	53	23	15	343	66	283

Table 5 shows Dr. Amato's review results broken down further by the categories assigned to the records during the screening process. For the ALMOPC and SAOPC samples, between one in four and one in five patients obviously had no recommended changes based on the initial screening. Of those patients requiring the next level of screening, two-thirds required medical record review. For the PolyPharm sample, all patients in the sample required a hardcopy pharmacy profile and 75% required medical record review. Unlike the other two samples, no patient profile from the PolyPharm sample put into category B had recommendations.

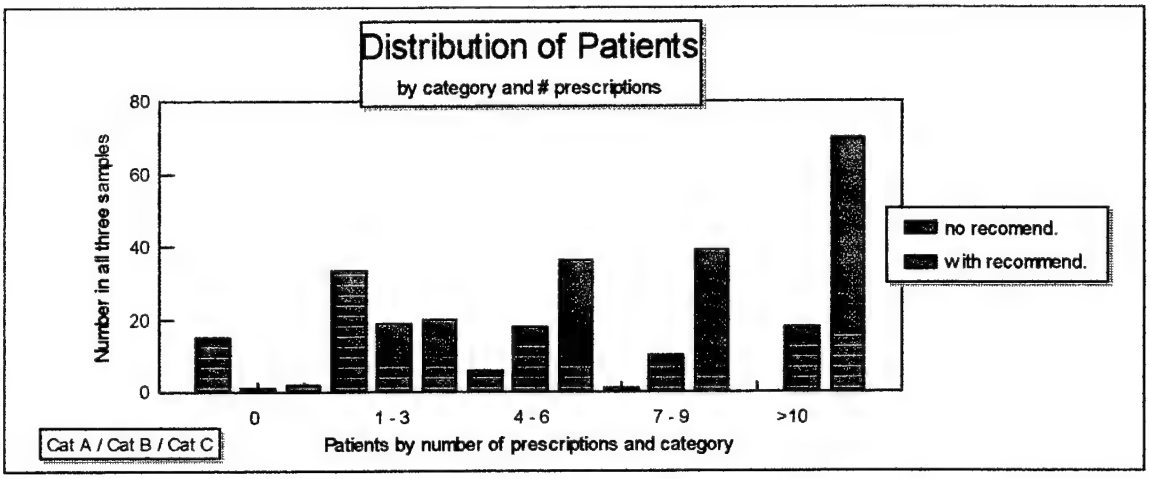
Figure 5 provides the frequency distribution for the categories, number of prescription items for each patient in the sample, and the number of patients with at least one recommendation. As the number of prescription items per patient rises, so does the

probability that the medical record will be required, as does the probability that the reviewing pharmacist will have made a change recommendation.

Table 5. Review Results by Category Assigned

Sample:	Cat. A	Cat. B	Cat. C
ALMOPC			
Patients	21	28	61
Prescriptions	37	109	454
Patients with recommendations	0	10	43
Total recommendations	0	17	100
SAOPC			
Patients	33	30	60
Prescriptions	67	190	352
Patients with recommendations	0	8	49
Total recommendations	0	10	107
PolyPharm			
Patients	0	12	45
Prescriptions	0	150	540
Patients with recommendations	0	0	24
Total recommendations	0	0	152

Figure 5. Sample Distribution by Category and Number of Prescribed Items.



Results were divided into gender and age categories to determine if any groups were over or under represented in terms of sample distribution, number of prescriptions per patient, number of recommendations per prescription. There were no striking differences among any of the demographic groups. Table 6 shows the results of the three samples reviewed by Dr. Amato broken down by sex and age.

Table 6. Review Results by Sex and Age

Sample:	ALMOPC					
	number	% of sample	prescriptions		recommendations	
			number	per patient	number	per prescription
Total:	109		606	5.6	117	0.19
Gender:						
Males	105	96.3%	572	5.45	103	0.18
Females	4	3.7%	34	8.5	14	0.14

Table 6. (cont.)

Sample:			ALMOPC			
	number	% of sample	prescriptions		recommendations	
			number	per patient	number	per prescription
Age:						
<40	5	4.6%	37	7.4	6	0.16
40-49	25	22.9%	128	4.2	23	0.18
50 - 59	15	13.8%	67	4.5	19	0.28
60 - 69	25	22.9%	137	5.5	29	0.21
70 - 79	31	28.4%	189	6.1	29	0.15
80 - 89	6	5.5%	34	5.7	7	0.21
>89	2	1.8%	14	7.0	7	0.29
Sample:			SAOPC			
	number	% of sample	prescriptions		recommendations	
			number	per patient	number	per prescription
Total:	123		609	5	117	0.19
Gender:						
Males	119	97%	579	4.9	112	0.19
Females	4	3%	30	7.5	5	0.17
Age:						
<40	8	6.5%	22	2.8	9	0.41
40-49	20	16.2%	143	7.2	21	0.15
50 - 59	16	13%	90	5.6	10	0.11
60 - 69	29	23.6%	163	5.6	41	0.25
70 - 79	40	32.5%	198	5.0	19	0.10
80 - 89	9	7.3%	9	5.7	15	0.29
>89	1	0.8%	5	5.0	2	0.40

Table 6. (cont.)

Sample:	PolyPharm					
	number	% of sample	prescriptions		recommendations	
			number	per patient	number	per prescription
Total:	57		680	11.9	152	0.22
Gender:						
Males	56	98%	677	12.1	150	0.22
Females	1	1.8%	13	13.0	2	0.15
Age:						
<40	1	1.8%	14	14.0	1	0.07
40-49	7	12.3%	108	15.4	11	0.10
50 - 59	6	10.5%	83	13.8	34	0.41
60 - 69	16	28.1%	170	10.6	51	0.3
70 - 79	25	43.9%	295	11.8	55	0.19
80 - 89	2	4%	20	10	0	0
>89	0	0%				

Bases for Pharmacists' Recommendations

An important part of this project was to determine and to document the basis for each recommendation by the pharmacists. The bases for the recommendations were not defined prior to the review; rather, each was defined on an "as needed" basis by the investigator. The pharmacist would write on each profile the recommended change and the reason for the change. For example: "cancel Naprosen - patient also taking Ibuprofen". This note would then be interpreted as a duplicate medication, and "duplicate medication" was the seventh reason to be defined. Thus, the first

recommendation was based on canceling future refills for an "as needed" (PRN) medication. The third recommendation was a change to a formulary drug; the fifth - no clinical indication; and so on. By the 60th recommendation of the first sample (ALMOPC) the first eleven bases had been defined. The twelfth was defined when several patients within the PolyPharm group clearly had a clinical need for the prescribed medication, but obviously had not been refilling the prescription as required. Prior to these recommendations, Code 3, "no clinical indication" had been adequate. Table 7 provides the definitions for each basis for a recommendation. Note that nine types of recommendations lead to cancellation of the prescription, while three lead to a change. The cancellations avoid CMOP cost; the changes do not. Table 8 shows the distribution of these bases for each of the four samples.

Table 7. Bases for Recommended Prescription Changes

Basis:	**Description**
1. D/C PRN Refills*	multiple refills were given for a medication taken occasionally on an as needed basis - cancel future refills
2. Change to Formulary Drug^	non-formulary medication was prescribed without justification in the record as to why formulary drug was not appropriate
3. No Clinical Indication*	no note in the medical record indicating the medication is necessary, or medication has been continued beyond the time indicated in the record without explanation
4. Clinical Contraindication*	the medical record indicates that there is a specific reason why the patient should not be on that particular medication

Table 7. (continued)

5. Change to Less Expensive Medication^	expensive formulary drug was prescribed without justification in the record as to why cheaper and equivalent alternative was not appropriate
6. Change Dosage^	prescribed dose falls outside the recommended range and no explanation in the record ~~as to why the same or an equivalent medication was also prescribed and no explanation as to why in the medical record~~
7. Duplicate Prescription*	self-explanatory
8. Patient Resides Outside the Region or Not STVHCS patient*	self-explanatory
9. Change to Improved Drug Regimen^	alternative dose, timing or drug has been shown to be more effective for the condition and no indication of clinical trial of the alternative in the record
10. Non-effective Regimen*	the prescribed drug has been shown not to be effective in treating the condition for which it was prescribed - no indication that an alternative is necessary
11. Patient Deceased*	self-explanatory
12. Patient not taking as prescribed *	there is a clear clinical indication for the medication, but the patient has not refilled it during the previous four months or is not taking the medication as prescribed.
* recommendation leads to cancellation	^ recommendation leads to item change (dose or drug)

Table 8. Distribution of Bases for Recommendations Among Samples.

Sample:	ALMOPC	SAOPC	PolyPharm	Staff Pharm.	Direct Supply Savings
Basis Code:					
1	14	18	7	7	$67.14 (1.4%)
2	14	2	4	6	$376.67 (7.6%)
3	30	47	50	25	$1498.55 (30.3%)
4	7	5	4	2	$90.78 (1.8%)
5	5	16	1	0	$418.54 (8.5%)
6	1	0	0	4	$79.28 (1.6%)
7	7	9	5	9	$330.70 (6.7%)
8	25	7	42	0	$1015.84 (20.6%)
9	1	4	3	3	$136.31 (2.8%)
10	4	9	0	0	$54.41 (1.1%)
11	9	0	13	0	$210.26 (4.3%)
12	0	0	23	16	$660.28 (13.4%
Totals: Cancellations:	96	95	144	58	$3927.89 (79.5%)
Changes:	21	22	8	8	$1010.8 (20.5%)

Cost-Avoidance Calculations Results

The cost avoided (incurred) for each recommendation was calculated as described in Chapter 2. CMOP cost savings were applied for only those recommendations resulting in a cancellation (see Table 8). Table 9 shows the results of these calculations.

Table 9. Impact on Cost by the Recommended Changes by Sample

Sample:	Number of Recommend.	Direct Supply Savings per Mo.	Total Savings with refills*	Total Savings with renewals*
ALMOPC	117	$1,173.41	$6,188.74	$22,343.26
Best Case^			**$5,941.19**	$21,449.53
Worst Case#			**$2,784.93**	$10,054.47
SAOPC	117	$908.32	$4,546.57	$17,498.41
Best Case^			**$4,364.71**	$16,798.47
Worst Case#			**$2,045.96**	$7,874.28
PolyPharm	152	$1,580.08	$6,947.64	$29,019.00
Best Case^			**$6,669.73**	$27,858.24
Worst Case#			**$3,126.44**	$13,058.55
Staff Pharm.	66	$1,230	$4,387.55	$20,400.35
Best Case^			**$4,212.05**	$19,584.34
Worst Case#			**$1,974.40**	$9,180.16

* direct supply costs per month times number of refills + $1.80 times canceled items times refills - $5.00 per change
^96% implementation (Carter & Heilling 1992)
#45% implementation (50% [Mason & Colley 1993] minus 5%)

Labor Cost Results

As described in Chapter 2, the reviewing pharmacists recorded the time spent reviewing the pharmacy profiles and medical records. With exception of the PolyPharm sample where only eight to twelve medical records were available at any given time, Dr. Amato was able to complete the review in several four to five hour sessions. Ms. Quezada reviewed one to several records at a time, recording the number of profiles and records reviewed, and the number of minutes needed. Consultation and physician review times were measured by direct observation of the time required for Dr. Amato to review all of the recommendations for the SAOPC sample with the SAOPC Chief. This session took one hour, but to account for the additional time required by each to actually implement the agreed upon changes this was doubled to two hours. Tables 10, 11, 12, and 13 report the results of the labor cost calculations for the four samples.

Table 10. Labor Cost Results: ALMOPC Sample

	Hours	$ PER HOUR	Activity Cost
Pharmacist:			
Profile Review	4	$37.00	$148.00
Record Review	9	$37.00	$333.00
Consultation	2	$37.00	$74.00
Physician:	2	$83.00	$166.00
Record Clerk*	2.1	$13.25	$27.83
Total Labor Cost for Sample:			**$748.83**

* 62 records pulled

Table 11. Labor Cost Results: SAOPC Sample

	Hours	$ PER HOUR	Activity Cost
Pharmacist:			
Profile Review	4	$37.00	$148.00
Record Review	5	$37.00	$185.00
Consultation	2	$37.00	$74.00
Physician:	2	$83.00	$166.00
Record Clerk*	1.6	$13.25	$21.20
Total Labor Cost for Sample:			**$594.20**
* 60 records pulled			

Table 12. Labor Cost Results: PolyPharm Sample

	Hours	$ PER HOUR	Activity Cost
Pharmacist:			
Profile Review	2	$37.00	$148.00
Record Review	8	$37.00	$296.00
Consultation	2	$37.00	$74.00
Physician:	2	$83.00	$166.00
Record Clerk*	1.5	$13.25	$19.88
Total Labor Cost for Sample:			**$703.88**
* 45 records pulled			

Table 13. Labor Cost Results: Staff Pharm. Sample

	Hours	$ PER HOUR	Activity Cost
Pharmacist:			
Profile Review	11	$28.00	$308.00
Record Review	6.5	$28.00	$182.00
Consultation	2	$28.00	$56.00
Physician:	2	$83.00	$166.00
Record Clerk*	1.5	$13.25	$19.88
Total Labor Cost for Sample:			**$731.88**
* 36 records pulled			

Cost-Minimization Results

As described in Chapter 2, a best and worst case cost-minimization ratio was calculated for each sample. These ratios were calculated by dividing the results from Table 9 by the results from Table 10-13. The highest ratio calculated was for the PolyPharm sample reviewed by Dr. Amato ($9.48 avoided for every $1 spent); the lowest was for the StaffPharm sample reviewed by Ms. Quezada ($2.70 avoided for every $1 spent). Table 14 shows these ratios.

Table 14. Cost Minimization Ratios

Sample:	Avoided Cost	Labor Cost	Ratio
ALMOPC:			
Best Case	$5,941.19	$748.83	7.93
Worst Case	$2,784.93	$748.83	3.72

Table 14. (cont.)

Sample:	Avoided Cost	Labor Cost	Ratio
SAOPC:			
Best Case	$4,364.71	$594.20	7.35
Worst Case	$2,045.96	$594.20	3.44
PolyPharm			
Best Case	$6,669.73	$703.88	9.48
Worst Case	$3,126.44	$703.88	4.44
Staff Pharm			
Best Case	$4,212.05	$731.88	5.76
Worst Case	$1,974.40	$731.88	2.7

The results from the record review process were also used to project the potential savings and cost ranges likely to be experienced should the STVHCS elect to adopt a clinical pharmacy case review program for outpatients. For these projections, the number of patients assigned to each of the outpatient activities were obtained from the STVHCS Medical Administration Service. The number of recommendations per patient (recommendation rate) was calculated for each of the three completed samples. For the Kerrville and Satellite Clinics Divisions, the rate for the SAOPC was used. The potential cost avoided per recommendation (savings rate) was calculated by dividing the direct supply savings from Table 9 by the number of recommendations for each sample. The review rate per 100 records for each sample was calculated by dividing the pharmacist time required to review that sample by the sample size. Finally, the labor cost rate for 100 records was calculated by multiplying the review rate by the hourly rate for a GS13, Step 5 clinical pharmacist ($38 per hour). Table 15 shows these projections.

Table 15. Projected Program Savings for STVHCS

	SAOPC	Corpus Christi OPC	McAllen OPC	Victoria OPC	Laredo OPC
population	7400	4500	5100	1600	2000
recommend. rate	1.05	1.05	1.05	1.05	1.05
# recommend.	7779	4725	5355	1680	2100
savings rate (per recommendation)	$38.86	$38.86	$38.86	$38.86	$38.86
potent. savings	$302,307.55	$183,611.48	$208,093.01	$65,284.08	$81,605.10
review rate	8.9 hrs/100 rec	8.9 hrs/100 rec	8.9 hrs/100 rec	8.9 hrs/100 rec	8.9 hrs/100 rec
pharmacist time	700 man-hrs	400 man-hrs	450 man-hrs	150 man-hrs	180 man-hrs
labor cost rate	$483/100 rec	$483/100 rec	$483/100 rec	$483/100 rec	$483/100 rec
tot. labor cost	$35,742.00	$21,735.00	$24,633.00	$7,728.00	$9,660.00
Best Case (96% implementation)	$254,473.25	$154,532.02	$175,136.29	$54,944.72	$68,680.90
Worst Case (45% implementation)	$100,296.40	$60,890.17	$69,008.86	$21,649.84	$27,062.30

Table 15. (cont.)

	ALMOPC	Kerrville Division	Total STVHCS	PolyPharm
population	29000	7500	48000	1970
recommendation rate	1.07	1.05	1.06	2.67
# recommend.	31128	7875	50880	5260
savings rate (per recommendation)	$52.90	$38.86	$46.28	$45.71
potent. savings	$1,646,545.50	$306,019.13	$2,354,684.00	$240,420.34
review rate	13.8 hrs/100 rec	8.9 hrs/100 rec	11.9 hrs/100 rec.	21 hrs/100 rec.
pharm. time	4000 man-hrs	670 man-hrs	5700 man-hrs	420 man-hrs
labor cost rate	$687/100 rec.	$483/100 rec	$606/100 rec	$1235/100 rec.
tot. labor cost	$199,230.00	$36,225.00	$290,880.00	$24,329.50
Best Case (96% implementation)	$1,381,453.68	$257,553.37	**$1,969,616.64**	$206,474.03
Worst Case (45% implementation)	$541,715.48	$101,483.61	**$768,727.80**	$83,859.65

CHAPTER 4

DISCUSSION

General

The purpose of this project was to determine if a clinical pharmacy case review program could result in sufficient cost-avoidance to pay for itself. The easiest way to make this determination is to examine the cost-minimization ratios reported in Table 14, looking for any that might exceed unity. For this project, the cost-minimization ratios range from 2.7 (Staff Pharm. sample, "Worst Case") to 9.48 (PolyPharm sample, "Best Case"). A second way to determine potential program effectiveness would be to examine the results of Table 15 and determine if the projected cost avoided exceeds the projected labor cost for the system as a whole, or any particular clinic setting. Once again, the program yields a substantial overall cost savings for all STVHCS clinics.

In order for this project to demonstrate a positive return, at least four conditions had to be met: 1) sufficient number of potential money-saving changes are extant; 2) these changes are relatively easy to detect by a clinical pharmacist reviewing pharmacy profiles and medical records; 3) treating physicians are willing to accept and implement a sufficient number of the recommended changes; and 4) implemented changes would actually result in some amount of future savings.

For this study, were there a sufficient number of potential changes? When this study was designed, the sample size of 100 was based partly on the assumption that 50%, 25%, and 10% of the records for the PolyPharm, ALMOPC, and SAOPC samples, respectively, would contain at least one prescription that could be changed. As it turned out, only 42% of the PolyPharm group had at least one recommendation; however, the rates for the ALMOPC and SAOPC groups far exceeded expectations at 49% and 46%, respectively. Thus, Dr. Amato found at least one recommendation in 46.4% of the 289 records she reviewed.

Perhaps a telling result is the number of recommended changes per prescription. For both the ALMOPC and SAOPC samples, almost one out of every five prescriptions could be canceled or changed to a cheaper alternative. For the PolyPharm sample more than one out of every five prescriptions were associated with a recommended change.

It was not enough to identify the recommendation. The pharmacists were also required to justify the change by citing one of twelve bases for the change. Thus, with almost one of every two records containing a recommendation, regardless of which sample the patient fell into, and one out of every five prescription items having a justified basis for change, the first condition is met. There is an adequate number of potential changes to justify the program.

Were the changes fairly easy to detect by the reviewing pharmacist? Each of the pharmacists developed her own screening method. However, both used the on-line pharmacy profile summary to determine obvious absence of recommended changes and the need for further screening. Through this method, Dr. Amato was able to eliminate 54

patients from further screening for the ALMOPC and SAOPC samples combined. Ms. Quezada was able to eliminate 53 patients.

The next step in the screening process was to print a copy of the extensive "Informational Prescription Profile". From this report, Dr. Amato developed potential recommended changes and determined if her review of the medical record was required to confirm the recommendations. The information on the profile was sufficient to eliminate another 18 patients from further recommendation, identify 27 recommendations that required no further confirmation, and identify 92 medical records that needed to be reviewed to confirm or eliminate over 200 recommended changes. Ms. Quezada was able to identify six Category B patients with 40 recommendations and eliminate another 17 patients from further consideration using this screening process.

Dr. Amato was able to complete the profile screening in four hours for both the ALMOPC and SAOPC groups. For this eight hours of effort, she eliminated a total of 108 patients from further consideration and identified 27 recommended changes. Ms. Quezada required eleven hours to complete the profile screening for only 91 patients, but she eliminated 76 from further consideration and identified 40 recommendations. The potential cost avoided just for the screening was $250 (.85 cost -minimization ratio) and $2000 (6.4 cost-minimization ratio) for Dr. Amato and Ms. Quezada, respectively.

The final step of the review process involved reviewing medical records to confirm or eliminate potential recommendations developed out of the screening process. Dr. Amato was able to review a total of 167 medical records in 22 hours for an average review time of 7.9 minutes per record. Ms. Quezada completed her review of 36 records

in 6.5 hours for an average review time of 10.8 minutes per record. Of the medical records Dr. Amato reviewed (Category Cs) from the ALMOPC and SAOPC samples (122), she confirmed at least one recommendation in over 75% (92 records) and confirmed a total of 207 recommendations in just 13 hours. Ms. Quezada was able to confirm a total of 26 recommendations from twelve of 15 Category C records (80%) she reviewed.

The above results indicate the recommended changes were relatively easy to identify, justify and confirm, both through pharmacy profile screening and medical record review. Thus, the second condition was met.

The third condition to be met was that recommended changes were actually adopted by the physicians. It was beyond the scope of this investigation to measure directly which of the recommendations would be accepted and what the projected cost savings were for those particular changes. However, two surrogates for recommendation implementation were employed as indirect measures of physician compliance.

As described in Chapters 2 and 3, the literature contained several reports of clinical pharmacy programs similar to the one described here. For several of these efforts, recommendation adoption rates exceeding 90% were reported. The highest rate reported was 96% (Carter & Heilling 1992); this is the rate used for the "best case". The lowest rate reported was 50% (Mason & Colley 1993). This rate was used to derive the "worst case" rate of 45% implementation. For each sample, all of the cost-minimization ratios for the "worst case", as reported on Table 14 exceeded unity. Thus, even if only 45% of the recommended changes were to be implemented, the third condition would be

met. In fact, using the projected figures for the STVHCS from Table 15, if only 12.5% of the recommendations were implemented, the cost-minimization ratio would still be at least equal to 1.

The second indirect measure of recommendation implementation came from the two physician consultation sessions. While the Chief, SAOPC was reviewing the SAOPC recommendations, she was asked to categorize each recommendation as: "No" (recommendation rejected out of hand), "Yes" (recommendation fully justified and could be implemented by Dr. Amato), or "LIP" (the patient's primary physician would have to review the recommendation before implementation, or "maybe"). For the 117 recommendations, only 1 were classified as "No", 99 were classified as "Yes", and 17 would be referred to the patient's physician. If only the "Yes" recommendations were implemented, the implementation rate for this surrogate would be almost 85%.

The final condition that would have to be met in order for a program such as this to be cost-effective is that implemented recommendations would have to result in much of the calculated savings. Projected savings are based on the assumption that the patients would have refilled each item the prescribed number of times had no intervention been taken. This is probably not a valid assumption. One could argue that most of the savings from several of the codes would never be realized. In fact, Basis Codes 8 (not a STVHCS patient), 11 (patient deceased), and 12 (patient not refilling item as prescribed), in particular, seem unlikely to yield many savings at all; yet these three codes account for 38.3% of the calculated direct supply savings (Table 8). On the other hand, some percentage of the canceled prescriptions would have been renewed automatically for

another year. Assuming that 50% of the projected savings would never have been realized and that 50% of the changed prescriptions would have been automatically renewed for another year, and applying these assumptions to the savings for each group as reported in Table 9, yields projected savings only slightly lower than the savings used to calculate the cost-minimization ratios. In fact, the projected savings for the Staff Pharm. sample increase slightly. Even if one were not willing to consider potential savings from renewed prescriptions, the product of the recommendation implementation rate and the rate of savings that were actually realized would have to be less than 0.125 for the entire system in order for the projected STVHCS cost-minimization ratio to be less than 1. For example, if the implementation rate were 75%, only 17% of projected savings would have to be realized to reach the break even point for the program.

The literature contains a number of reports demonstrating the effectiveness of DUR and clinical pharmacy review programs in a variety of health care settings. It was, therefore, no surprise to find that the STVHCS met the four conditions for an effective program and that cost-minimization ratios exceeded unity by a substantial margin. In fact, the relative number of potential changes per record and the cost-minimization ratios reported here are higher than those reported in the literature. In retrospect, this could have been anticipated.

At least two factors inherent to the Veterans Health Care System (and the military health care systems) are not present in the private sector, and contribute to prescribing inefficiencies. Within the STVHCS, patients are likely to see more than one provider. As each provider cares for the patient, new prescriptions are added. No one provider has

an incentive to change or cancel unneeded prescriptions or refills prescribed by another provider. This is true for even those patients with a designated primary care physician. In private sector health care systems, the principle role of the primary care gatekeeper is to contain costs through controlling access to specialists and coordinating all health care provided a patient. Within the federal systems, the role of the primary care provider is to coordinate access to specialists. Once a patient is given a prescription by a specialist, and that prescription expires, the primary care gatekeeper has the choice of referring the patient back to the specialist who originally wrote the prescription, changing the prescription profile, or automatically renewing the prescriptions as written. Unlike other systems, there is no financial incentive for one physician to change another physician's prescriptions, and there is a definite disincentive for attempting to refer every patient back to the original prescribing physician, i.e. inadequate access.

Additionally, a process has been established that makes it very easy for any physician to renew every one of a patient's medications for up to twelve months by using the action pharmacy profile (the physician merely circles the number of refills for each item and signs the profile - no documentation of the continued need for the medication is required). Thus, unless a therapeutic regimen is not working or a patient complains about side effects, prescription profiles might not ever change. Even when a physician does have reason to change a treatment regimen, there is no process to assure superfluous prescription items are canceled.

Finally, in other health care systems, the patient has a financial incentive not to refill medications that are no longer needed or are not apparently effective. This

incentive does not exist for most veterans and DoD beneficiaries. Additionally, there are anecdotal reports that some veterans believe that if they do not refill medications as prescribed (even if they're no longer taking the medication), they will lose their benefits.

The clinical pharmacy case review program described in this project adds a financial incentive into the outpatient pharmacy process. In order for reviewing pharmacists to justify the continuation of the program, they would have to demonstrate continued cost-avoidance to pay for the cost of the program. Additionally, physicians would have a non-financial incentive to alter prescribing (especially refilling and renewing) practices, in that they would be given the review standards to use as prescribing guidelines and they would be aware that individual prescribing practices were being monitored.

Targeted Groups

If the STVHCS managers were to implement a clinical pharmacy case review program, they would try to design the program to be as efficient as possible in terms of identifying the maximum number of cost-avoiding recommendations in the least amount of time. One means of increasing program efficiency would be either to target easily identified subpopulations likely to yield high recommendation rates, or to eliminate subpopulations likely to yield low recommendation rates. Identifying potential target groups was the rationale for comparing recommendation rates for a general out-patient clinic (SAOPC) and specialty-based outpatient clinic (ALMOPC), the genders, age groups, and the number of prescription items per patient.

Originally, it was believed that the ALMOPC sample would yield much higher recommendation rates than the SAOPC sample. While the former group did have on the average more prescription items per patient (109 patients - 606 items) than the latter group (123 patients - 609 items), the number of recommendations identified per prescription (117 recommendations for 606 and 609 items, respectively) was almost exactly the same. Even though the potential cost avoidance for the ALMOPC sample exceeded the cost avoidance for the SAOPC sample by 36%, the labor cost for the latter also exceeded the former by 26%. Thus, the calculated cost-minimization ratios were very similar. There appears to be no basis for either targeting the specialty-based outpatient clinic patients or eliminating the general outpatient clinic patients.

In regards to targeting review by sex, only 13 female patients were in all four samples combined. Although this was an insufficient quantity to conduct in-depth analysis, there appeared to be no reason to either target or eliminate patients based on gender because both genders had a fairly high recommendation rate.

The three samples reviewed by Dr. Amato were divided into age categories, and age-specific rates for number of prescriptions per patient and number of recommendations per prescription were calculated (Table 6). Upon superficial examination of these data, it was concluded that no one age group was sufficiently over- or under-represented to justify targeting or eliminating the group. Herein lies an interesting point. Several articles reviewed in Chapter 1 suggest strong associations among aging, the number of prescription items per patient, and the average pharmacy cost per patient (Stuart & Coulson 1993, Chrischilles 1988, Purves & Edwards 1993). In

fact, several of the STVHCS medical staff believe that an aging, sicker population explains much of the increase in pharmacy expenditures experienced by the system. While the data in Table 6 do indicate that patients over 60 years of age make up a large part of the sample (especially the PolyPharm sample), the number of prescriptions per patient show no consistent trend with age. Therefore, there appeared to be no indication to target review by age.

Figure 5 displayed the distribution of patients by category and number of prescriptions. The probability that the initial screening process will be sufficient to confirm recommendations declines as the number of prescriptions for each patient rises. However, even profiles containing one to three items have a 36% (19 of 53) chance of containing at least one recommended change. Consequently, patients with few medications should not be eliminated from review.

For this project, a group of patients with more than nine prescriptions were targeted for the PolyPharm sample. The results of the review were consistently better for this sample when compared to the other two samples with a full range of prescription items per patient. Also, because so few of the records met the initial screening criteria, pharmacist screening time was reduced and the labor cost for this sample was somewhat lower than the other samples. Thus, the cost-minimization ratios for the PolyPharm sample were higher. On the down side is the very low number of records readily available from the PolyPharm sample. Record requests had to be submitted repeatedly to achieve an adequate number of these patients' records.

Bases for Pharmacists' Recommendations

It was important that the reviewing pharmacist provide a clear justification for every recommendation. These bases for recommendations serve two purposes: they provide a precise rationale to the physician as to why the change or cancellation should be made, and they serve as the bases for review criteria.

Several of the articles reviewed provided different lists the authors used to describe problem areas or justifications for changes (*e.g.* Kralewski, Wertheimer & Ratner 1994). Although none of the actual lists were used for this project, many of the bases used here are very similar to those published elsewhere. Twelve categories were required to provide the basis for each of the recommendations. Code 3, "No clinical indication" (29%) was the most common single reason given for a recommendation. Code 8, "not a STVHCS patient" accounted for another 14%. The several codes that seem most likely to reflect questionable quality of care, codes 4 (contraindication), 6 (unusual dose), 9 (improved regimen), and 10 (non-effective regimen) were used to justify approximately 9% of the recommendations.

Each of the justifications could be used to define pharmacy case review standards for a future review program. Such standards could both specify actions for a reviewing pharmacist and serve as prescribing guidelines for physicians. For example: Code 1 (cancel refills for a PRN medication) could be rewritten to authorize the reviewing pharmacist to cancel any more than two refills for a PRN medication. Code 2 (change to a formulary item) and 5 (change to a cheaper item) could be rewritten to authorize an automatic change to a cheaper drug, unless the prescribing physician made a statement in

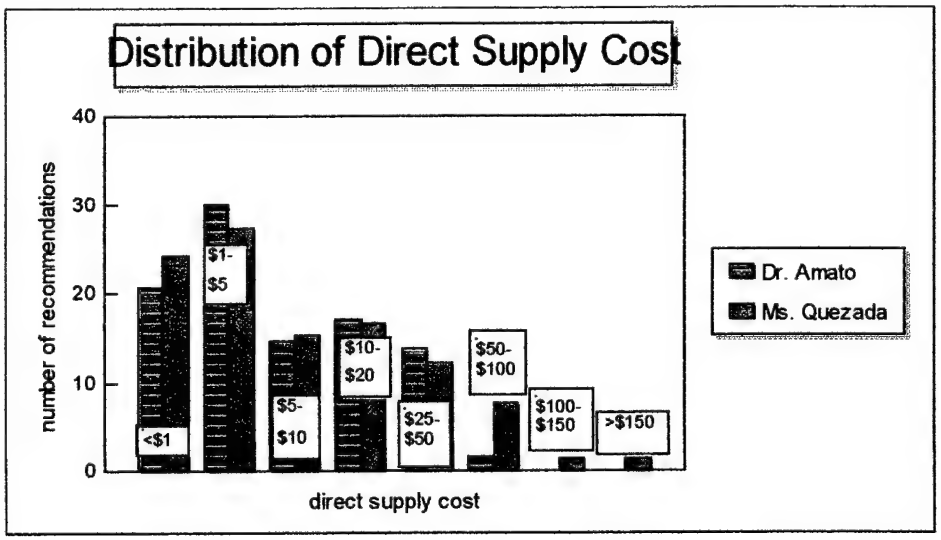
the medical record as to why the non-formulary or more expensive medication was needed. When written as standards, several of the other codes (e.g. Code 6 "Change Dosage") would have to be written in such a way that the change would be recommended to the physician, rather than automatically implemented by the pharmacist.

Inter-Reviewer Differences

The original intent of this project was to have both pharmacists review all three samples, to include 10% of the profiles reviewed by both pharmacists. Unfortunately, Ms. Quezada was only able to complete 89 patients from the ALMOPC sample. Thus, only casual observations can be made regarding inter-reviewer differences.

Figure 6 represents the distribution of direct supply cost per recommended change for the reviewers. With the exception of approximately ten high cost changes identified by Ms. Quezada, the relative distributions are almost identical.

Figure 6. Direct supply cost related to individual recommendations (ALMOPC)



The time Ms. Quezada required to complete the review of one sample of 91 ALMOPC patients was 17.5 hours. Dr. Amato completed her review of 123 ALMOPC patients in 13 hours. On a per record basis, Dr. Amato finished this one sample in approximately 1/2 the time required by Ms. Quezada. This apparent difference seems likely to be related primarily to the process used by each pharmacist. Although these data are extremely limited, it appears that setting aside specific blocks of time dedicated to the review process is more efficient than reviewing records throughout the day as time becomes available.

Project Limitations

Investigator Bias.

All participants in this project were motivated to help this project succeed. The reviewing pharmacists knew that the faster they completed the review process, the less the program would cost. Also, the more recommendations they identified, the higher the cost avoidance. Additionally, because they knew that the recommendations they were identifying were not actually going to be implemented, it was quite possible that the pharmacist would make cost-avoiding changes that she knew would never be acceptable to the physician. This potential bias was mitigated by the need to justify each recommendation to the investigator and a reviewing physician.

Likewise, the reviewing physicians were biased for project success. This bias plus the knowledge that saying "yes" to a recommendation did not mean its implementation severely limits use of the results of the physician review process as a

surrogate for recommendation implementation. This bias is mitigated by the use of the second surrogate for implementation - implementation rates from the published literature. Clearly, direct measurement of actual implementation rates would have been preferable to the use of surrogates, and would have helped reduce the impact of investigator bias on the project outcome. Unfortunately, direct measurement of implementation was beyond the scope of this study. However, measurement of implementation rates should be made an integral part of a clinical pharmacy case review program implemented by the STVHCS.

Nature of Data.

The review process described is retrospective. Thus, all cost-avoidance rates are based on point-prevalence data about previously unreviewed active prescriptions and refills. This imposes several limitations on the study.

One limitation concerns program implementation. The potential cost-avoided and labor cost totals reported for the STVHCS were based on a one-time review of all outpatient pharmacy profiles within the system and an anticipated recommendation rate of approximately one in five active prescriptions. From this study, there is no way to determine how long it took for this high rate of inappropriate prescriptions to develop or how often it would be necessary to re-review the records. On one hand, every outpatient visit is an opportunity to renew unnecessary medications - even those that had previously been canceled via the review program. On the other hand, as soon as review criteria are published, physicians are likely to alter prescribing practices and every outpatient visit becomes an opportunity to correct prescription problems before they are detected by a

reviewing pharmacist. As this occurs, direct measures of review program effectiveness, such as the number of recommendations per 100 prescriptions, will begin to decline and impact of the program on reducing pharmacy cost will be underestimated.

Another limitation concerns using active refill data to calculate future savings. This requires the assumption that some proportion of these active prescriptions will be refilled as prescribed. Because this project included no means to test this assumption, sensitivity analysis was used. For example, although it seems appropriate to cancel all active prescriptions for a deceased patient (eliminating the possibility that someone else can use the refills), and, even though there was no way to determine if any of the refills would ever have been issued, the potential cost avoided by the cancellations were included in cost-minimization ratio calculation.

Finally, these data allow no way to determine when any particular prescription became unnecessary. Obviously, the sooner an unnecessary or costly prescription can be canceled or changed, the greater the cost-avoidance.

These limitations can be addressed when the actual review program is implemented. By adopting review standards as prescribing policy, future inappropriate prescriptions can be prevented and those prescriptions that become unnecessary can be canceled or changed in the outpatient clinic rather than when that record happens to be reviewed. Additionally, when program effectiveness is assessed, the indirect affect of the program on total outpatient pharmacy expenditures over time should be considered along with direct measures of effectiveness.

Quality Improvement.

For this project, the only potential benefit measured was the potential cost-avoidance. Clearly, an additional benefit derived from clinical pharmacy case review would be improved quality of care. Implementation of those recommended changes justified by Bases Codes: 4 - "clinical contraindication", 6 - "change dosage", 7 - "duplicate medication", 9 - "change to improved drug regimen, and 10 "non-effective regimen" should improve the quality of care directly. Implementation of recommendations based on codes 3 - "no clinical indication" and 12 - "patient not taking as prescribed", can improve quality of care indirectly by forcing those patients who still require the canceled medications to make appointments. Finally, implementation of the recommendations based on codes 2 "change to formulary drug", 3 "no clinical indication" and 5 "change to less expensive medication" could have a negative impact on quality if not coordinated with a physician familiar with the patient's condition.

Reviewer Learning

As the project was being designed, it seemed likely that the reviewing pharmacists would become more efficient in reviewing pharmacy profiles and medical records as the project progressed. Labor cost and review rates were going to be adjusted for any learning efficiency detected. As it turned out, learning efficiency was not detected and no adjustments were made.

The are several possible explanations for the lack of a detectable learning curve. Both Dr. Amato and Ms. Quezada already had considerable experience reviewing

pharmacy profiles. It is possible that neither became more efficient during the review process. Also, it was not anticipated that Dr. Amato could complete all but one of the review steps for all three samples in one time block for each. Thus, the mechanism developed for tracking review time was not sufficiently sensitive to determine if those individual records reviewed early in the process took longer than those reviewed later.

Ms. Quezada did document the number of pharmacy profiles and records reviewed in small blocks. The absence of detectable learned efficiency may be in part due to the fact that Ms. Quezada only reviewed 89 profiles over a several month period.

CHAPTER 5

CONCLUSIONS/RECOMMENDATIONS

Direct supply outpatient pharmacy expenditures for the STVHCS are consistently increasing at the rate of 1.4% per month. Of this increase, 0.9% can be attributed to a steady increase in the number of prescriptions issued on a per visit basis. The basic hypotheses for this project were that some percentage of the outpatient prescriptions were no longer necessary or had cheaper alternatives and that pharmacy cost could be minimized by implementing appropriate changes in these prescriptions. The purpose of the project was to determine if the cost of a clinical pharmacy case review program designed to identify and implement the recommendations was less than pharmacy cost-avoidance.

Based on the review of over four hundred pharmacy profiles and over 190 medical records from four randomized samples of STVHCS patients, it is concluded that up to one in five (20%) of the active outpatient prescriptions could be canceled or changed to a cheaper alternative. This rate was fairly consistent regardless of the age or sex of the patient.

Cost-minimization ratios for each sample were calculated by dividing the potential cost savings associated with best and worst case implementation rates by the labor cost associated with identifying and implementing the recommended changes.

Cost-minimization ratios ranged from a high of 9.48 to a low of 2.7. Thus, it is concluded that potential savings far outweigh the cost of the labor associated with the program.

Sample results were extrapolated for all outpatients within the STVHCS. At the cost of three full-time equivalent clinical pharmacy positions and approximately $291,000 for labor, potential savings from a comprehensive clinical pharmacy case review program could exceed 2.3 million dollars. Because the project was not designed to measure recommendation implementation rates, and because there is no way to determine how many of the changed or canceled refills would have actually been filled, sensitivity analysis was performed. A review program would result in pharmacy cost savings even if the product of the implementation rate and realized refill rate exceeded 0.124.

The pharmacist reviewers justified each recommended change; twelve recommendation bases were defined. Each of these bases can serve as the basis for case review standards and prescribing practice guidelines.

These results are believed to be generalizable to any health care system in which patients can see multiple providers, and where no identified health care provider has an incentive to reduce pharmacy cost. The absence of patient incentive to not refill unnecessary prescriptions compounds the problem. Thus, a clinical pharmacy case review program would likely benefit both Department of Defense and Department of Veterans Affairs health care facilities.

Recommendations

The STVHCS should implement a clinical pharmacy case review program by:

1) Assigning a full-time clinical pharmacist to develop, implement and manage the program.

2) Developing specific pharmacy review standards and prescribing practice guidelines.

3) Assigning at least two clinical pharmacists half-time to assist the managing pharmacist with the review.

4) Establishing a goal for the completion of the review of all pharmacy profiles in the STVHCS within the next two years.

5) Continuing the program at an appropriately reduced level upon the completion of the comprehensive review.

Program cost-minimization outcomes should be measured by:

1) Determining the actual labor cost associated with the program.

2) Determining the potential savings associated with recommended changes.

3) Determining the savings associated with those prescription changes actually implemented.

4) Comparing actual outpatient pharmacy expenditures over time with expenditures forecasted based on current spending rate increases.

Finally, if the program is shown to significantly reduce pharmacy expenditures, publish the results and expand the program to other DoD and DVA facilities.

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